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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,631

11/07/2005

Beate Schmidt

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EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

04/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,631	<b>Applicant(s)</b> SCHMIDT, BEATE	
	<b>Examiner</b> Sean Basquill	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7 Dec 2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 19-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 17 February 2009.

Applicant's election with traverse of Claims 1-18 in the reply filed on 17 February 2009 is acknowledged. The traversal is on the ground that Groups I and II as outlined by the examiner share a special technical feature, namely crystalline ciclesonide. This is not found persuasive because the crystalline ciclesonide of Group II was well known in the art prior to the applicant's invention, therefore the technical feature shared by Groups I and II is not, by definition, special within the meaning of PCT Rule 13.2.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-27 having been withdrawn as directed to a nonelected invention, Instant Claims 1-18 are presented for examination.

### ***Priority***

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

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If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) **must be included in the first sentence(s) of the specification following the title or in an application data sheet.** For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due

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under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Claim Objections***

3. Claims 10 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, Claim 1, from which both Claims 10 and 13 depend, already claim as the compound of Formula I 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione [11-beta,16-alpha (R,S)], and ciclesonide, respectively.

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***Claim Rejections - 35 USC § 112 Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, both claims refer to “the compound of formula 1,” as described in Claim 1, in a particular epimeric ratio. However, Claims 11 and 12 fail to indicate whether the claimed ratio refers to the compound of Formula 1 before or after the recrystallization process as claimed has taken place. In other words, the Claims fail to clearly indicate whether the limitation applies to the starting material or product obtained by the process as claimed, and are rendered indefinite as a result.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Patent Application WO98/09982 (hereinafter "Amschler") (of record), in view of the Merck Manual (1996).

Amschler describes a process of R-epimer enrichment of 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione [11-beta,16-alpha (R,S)] (hereinafter "ciclesonide") comprising dissolving the ciclesonide in a suitable water-miscible solvent such as acetone or ethanol, "expediently" at elevated temperature such as the boiling point of the solvent used. (Pg.2). Water is then added to the solution and then cooled with vigorous stirring to precipitate as finely crystalline a product as possible. (Id.) To further the microcrystallization as described, Amschler advises that the cooling should be carried out slowly, indicating a period of between 2-10 hours is preferred. (Id.). Amschler then indicates the precipitate is collected in a manner known to the skilled artisan, such as by filtration. (Pg.3). In a particular embodiment, ciclesonide is dissolved in boiling ethanol, water is added to the solution with vigorous stirring and allowed to cool to room temperature, and the precipitate is collected by filtration, washed, and allowed to dry. (Pg.4). A similar process is described using acetone as the organic solvent. (Pg.5). Amschler prefers that the starting material already represent an enrichment of the R isomer, in particular where the R isomer constitutes more than 85% of the epimeric mixture. (Pg.3). The process described by Amschler, which can be repeated if necessary, is capable of producing an R-epimeric enrichment of greater than 99%. (Pg.1). Amschler additionally indicates that the ciclesonide to be recrystallized may be synthesized by the acylation of the 21-substituted hydroxyl derivative. (Pg.3).

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Amschler does not describe the order of steps taken in the recrystallization as put forth in the instant application, nor are particular temperature ranges of solvent systems as claimed used for the recrystallization described.

The Merck Manual indicates that the boiling point of Acetone is 56.5°C (Pg. 12, Entry 64), and the boiling point of ethanol is 78°C. (Pg. 641, Entry 3806).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to modify the procedure of Amschler to arrive at the process as claimed in the instant application. One having ordinary skill in the art would have been motivated to do so because MPEP § 2144.04(IV)(C) indicates that the selection of any order of mixing ingredients known in the prior art is *prima facie* obvious. In addition, the modification of the experimental examples described in Amschler to achieve a solvent system temperature within the ranges as claimed represents no more than optimization through routine experimentation of the general conditions known in the art. MPEP § 2144.05(II). One having ordinary skill in the art would have been motivated to do so because of the express teaching of Amschler that simply "elevated temperatures" are preferred. The skilled artisan would have recognized the upper limit of these elevated temperatures are necessarily bound by the boiling point of the particular solvent chosen, and experimented within that range in order to best optimize the reaction conditions. Furthermore, Claims 16 and 17, specifically the language "where the particle size is characterized by an x50..." simply express the intended result of the positively recited process steps of the claims from which they depend, and accordingly do not limit the scope of the claims as presented. MPEP § 2111.04.

### ***Conclusion***



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No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill  
Art Unit 1612

/Brandon J Fetterolf/  
Primary Examiner, Art Unit 1642